HIGHLY CONFIDENTIAL ATTORNEYS' EYES ONLY

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff/Counterclaim Defendant, v. INTUITIVE SURGICAL, INC., Defendant/Counterclaim Plaintiff.	Case No. 3:21-cv-03496-VC

EXPERT REPORT OF CHRISTY FOREMAN, MBE

Senior Consultant, Biologics Consulting Group

January 18, 2023

This report contains confidential material and is subject to the order governing the production, exchange and filing of confidential information in this matter.

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necessary to develop my opinions regarding the activities at issue. The methods that I used are similar to the methods that I have employed throughout my career, including those methods that I used as a reviewer, manager and senior manager at the Food and Drug Administration and as a consultant to medical device companies.

A. Opinion 1 – Remanufacturing medical devices is a manufacturing activity, which is subject to FDA regulatory requirements, including premarket notification, registration, recall, medical device reporting, unique device identification, and postmarket surveillance among others.

68. Remanufacturing is clearly defined by FDA in existing regulations.

69. Plaintiff and the relevant third parties in this case have suggested that the definition of "remanufacturing" is a "murky area" because FDA has not published final guidance on all distinctions between remanufacturing and servicing.[43] But FDA's definition of remanufacturing has been clear since the promulgation of 21 CFR 820 in 1996,[44] and there is no doubt that a party that engages in the activities described in the regulation is a remanufacturer.

70. 21 CFR Part 820 (the Quality System Regulation) (the "QSR") provides the FDA regulatory requirements for good manufacturing practices for medical devices. FDA explained: "The provisions of this part shall be applicable to any finished device as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico."[45]

[43] Intuitive-00706083, at -6086.

[44] 61 Fed Reg. 52602 (Oct. 7, 1996).

[45] 21 CFR § 820.1(a)(2).